

UNITED STATES DISTRICT COURT
DISTRICT OF NEVADA

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TAMARA CARTER and DAVID CARTER,
Plaintiffs,
v.
JOHNSON & JOHNSON; ETHICON, INC.;
and ETHICON LLC,
Defendants.

Case No. 2:20-cv-01232-KJD-VCF

ORDER

Presently before the Court is Defendant's Motion to Limit Testimony of Prof. Dr. Med. Uwe Klinge (#198). Plaintiffs responded in opposition (#204) and Defendant replied (#215).

I. Factual and Procedural Background

This is a products liability action involving two prescription medical devices— Prolift and TVT. On July 23, 2010, at St. Rose Dominican Hospital in Las Vegas, Nevada, Dr. Gregory Hsieh implanted a Prolift device for Plaintiff Tamara Carter's ("Mrs. Carter") posterior pelvic prolapse and a TVT mid-urethral sling for Mrs. Carter's stress urinary incontinence ("SUI"). Mrs. Carter alleges that these medical devices caused her injuries, and that Defendants are liable under claims of strict liability for failure to warn and for design defect. Her husband, Plaintiff David Carter ("Mr. Carter") raises a loss of consortium claim. Additionally, Plaintiffs claim that Defendants' conduct was malicious, oppressive, willful, wanton, reckless, and grossly negligent. Defendants ("Ethicon") deny Plaintiffs' allegations and assert that Prolift and TVT were state of the art at the time of implant, that Mrs. Carter's alleged injuries pre-dated her surgery, that Mrs. Carter assumed the risks, and that Mrs. Carter's own actions contributed to her injuries.

Dr. Klinge is a general and abdominal surgeon who has used Prolene mesh for hernia repair and treated Prolene-mesh-related complications in patients. He has also spent over twenty years

1 studying Prolene and other surgical meshes, and ten of those years were spent consulting
 2 Ethicon. Dr. Klinge has been hired by Mrs. and Mr. Carter to provide expert testimony about the
 3 design of and alternatives to Ethicon meshes used in the treatment of stress urinary incontinence
 4 (“SUI”) and pelvic organ prolapse (“POP”), including TVT and Prolift Ethicon devices. Ethicon
 5 objects to Dr. Klinge offering expert opinion and argue it is unreliable, untrustworthy, or
 6 otherwise inadmissible.

7 II. Analysis

8 A. Legal Standard

9 Fed. R. Evid. 702 permits a “witness who is qualified as an expert by knowledge, skill,
 10 experience, training, or education [to] testify in the form of an opinion or otherwise if: (a) the
 11 expert’s scientific, technical, or other specialized knowledge will help the trier of fact to
 12 understand the evidence or to determine a fact in issue; (b) the testimony is based on sufficient
 13 facts or data; (c) the testimony is the product of reliable principles and methods; and (d) the
 14 expert has reliably applied the principles and methods to the facts of the case.” The Supreme
 15 Court gave expanded direction on Rule 702 in Daubert v. Merrell Dow Pharmaceuticals, Inc.,
 16 509 U.S. 579 (1993). In Daubert, the Court held that Rule 702 imposed “a special obligation
 17 upon a trial judge to ‘ensure that any and all scientific testimony... is not only relevant, but
 18 reliable.’” See Kumho Tire Co. v. Carmichael, 526 U.S. 137 (1999). The Court expanded this
 19 gatekeeping obligation to all expert testimony. Id. at 147. Daubert “established that, faced with a
 20 proffer of expert scientific testimony, the trial judge, in making the initial determination whether
 21 to admit the evidence, must determine whether the expert’s testimony reflects (1) “scientific
 22 knowledge,” and (2) will assist the trier of fact to understand or determine a material fact at
 23 issue.” Daubert, 509 U.S. at 592. The “focus must be solely on principles and methodology, not
 24 on the conclusions that they generate.” Id. at 595.

25 The Ninth Circuit has emphasized that “Rule 702 is applied consistent with the liberal thrust
 26 of the Federal Rules and their general approach of relaxing the traditional barrier to opinion
 27 testimony.” Jinro Am. Inc. v. Secure Investments, Inc., 266 F.3d 993, 1004 (9th Cir. 2001). “An
 28 expert witness—unlike other witnesses—is permitted wide latitude to offer opinions, including

1 those that are not based on firsthand knowledge or observation, so long as the expert’s opinion
 2 [has] a reliable basis in the knowledge and experience of his discipline.” Id. (citations and
 3 quotation marks omitted).

4 In Daubert, the Court also clarified that parties should not be “overly pessimistic about the
 5 capabilities of the jury and of the adversary system generally.” Daubert, 509 U.S. at 596.
 6 “Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the
 7 burden of proof are the traditional and appropriate means of attacking shaky but admissible
 8 evidence.” Id. “The role of the Court is not to determine ‘the correctness of the expert’s
 9 conclusions but the soundness of his methodology.’” Great W. Air, LLC v. Cirrus Design
 10 Corporation, No. 2:16-CV-02656-JAD-EJY, 2019 WL 6529046, *3 (D. Nev. 2019). “The judge
 11 is supposed to screen the jury from unreliable nonsense opinions... [t]he district court is not
 12 tasked with deciding whether the expert is right or wrong, just whether his testimony has
 13 substance such that it would be helpful to a jury.” Id. at 4.

14 **B. Dr. Klinge’s Opinions About Alternative Designs to the Prolene Mesh Sed**
 15 **in Ethicon’s SUI Products**

16 i. Ultrapro

17 Ethicon argues that Dr. Klinge’s opinions regarding alternative designs being safer than the
 18 Prolene mesh used in TVT should be precluded because they are not supported by testing or
 19 relevant scientific literature, and because they are speculative. (#198, at 4–5). Ethicon argues that
 20 Dr. Klinge has no reliable basis to claim that Ultrapro, a mesh used in hernia repair, would be
 21 safer and more effective for treating SUI because he cannot point to any studies supporting his
 22 conclusion. Id. Plaintiffs responded, arguing that his opinions are reliable and are not
 23 speculative. (#204, at 5–6). Plaintiffs reference several studies Dr. Klinge relied on to support his
 24 conclusion that Ultrapro is superior to Prolene because Ultrapro has larger-pores and is lighter-
 25 weight, and this decreases negative tissue response. Id. at 6. Ethicon replied to this argument and
 26 claim that the studies Dr. Klinge rely on are disconnected from the relevant issues and thus
 27 cannot provide reliable support. (#215, at 2–3).

28 Daubert makes clear that scientific expert testimony must be relevant and reliable. Daubert,

1 509 U.S. 579 at 589. It also makes clear that shaky but admissible evidence is to be dealt with
2 through cross-examination, presentation of contrary evidence, and careful jury instruction. Id. at
3 596. The Court finds that Dr. Klinge’s testimony is admissible.

4 In a deposition, Dr. Klinge says that Ultrapro, in its present form has advantages in
5 comparison to the Prolene material in regard to tissue response. (#198-7, at 25). He also states
6 that Ultrapro still has some disadvantages with respect to the structural stability, such that he
7 “wouldn’t like to have [it] in my body.” Id. When asked if his expert opinion was that Ethicon’s
8 Ultrapro mesh was an appropriate safer alternative design for the treatment of SUI, Dr. Klinge
9 said that Prolene’s small pores and amount of material create risks, and that reducing the material
10 and making larger pores would reduce those risks, but also that he is unable to predict now
11 whether Ultrapro will work better over time or create new problems. Id. He expressed that he has
12 “concerns for both” Prolene and Ultrapro and that Ultrapro’s pores can collapse under small
13 forces. Id. Dr. Klinge also stated he believed Ultrapro is still better than Prolene. Id. Dr. Klinge
14 then goes on to explain what kind of testing he would do to compare the use of Ultrapro and
15 Prolene mesh for the treatment of SUI and implies that those tests have not been done. Id. at 26.

16 However, Dr. Klinge bases those opinions on his study of mesh and the principles that
17 lighter-weight, larger-pore mesh is better. Dr. Klinge also backs up that opinion with reliable
18 scientific literature. (#198-1, at 9–16). Defendant will have the opportunity to cross-examine Dr.
19 Klinge in front of a jury, and present evidence of the weaknesses Dr. Klinge believes still exist
20 regarding Ultrapro, and it will be up to the jury to weigh the evidence.

21 The Court also finds that Defendant’s objection to the reliability of the studies Dr. Klinge
22 uses is unfounded. The Ninth Circuit has stated that “while studies involving similar but not
23 identical situations may be helpful, an expert must set forth the steps used to reach the
24 conclusion that the research is applicable. Domingo ex rel. Domingo v. T.K., 289 F.3d 600, 606
25 (9th Cir. 2002). In a deposition where Dr. Klinge is questioned about the Okulu study
26 specifically, he explains why the study was enlightening regarding a special way to use Ultrapro
27 that would diminish the risk of pore collapse and that if used in that way, it “maybe is a good
28 idea to have it.” The Court finds that Dr. Klinge’s expansive experience in using mesh and in

1 studying mesh design, as well as his explanation about the steps he has used to reach the
 2 conclusion that Ultrapro can work better than Prolene meets the standard set by the Ninth
 3 Circuit. Again, Defendant can cross-examine Dr. Klinge about the nuances of these studies, but
 4 the Court is tasked only with screening the jury from unreliable nonsense opinions, and the Court
 5 finds the studies referenced are reliable. See Great W. Air, LLC, 2019 WL 6529046.

6 ii. Other Designs

7 Ethicon asks the Court to limit his alternative design opinions to only PVDF because he has
 8 not disclosed any other design that he opined is a safer alternative to Prolene for the treatment of
 9 POP. (#198, at 8). Ethicon also argues that if the Court finds he did adequately state in his expert
 10 report that other devices worked better, he should still be precluded from testifying because those
 11 opinions are unsupported by testing or scientific literature. Id. Ethicon points again to Ultrapro
 12 and argues that Dr. Klinge has not specifically stated that Ultrapro would have been safer than
 13 Prolift in treating POP. Id. Mrs. and Mr. Carter responded and argued that Dr. Klinge did opine
 14 in his report about alternatives that would have been safer because he discusses that materials
 15 like Ultrapro that are lighter-weight and have larger-pores, are better than Prolene. (#204, at 8).
 16 The Court finds that Dr. Klinge has not explicitly stated in his POP report that Ultrapro is a
 17 better alternative to Prolene. However, Dr. Klinge has sufficiently supported his conclusion that
 18 lighter-weight, larger-pore material is better for treating POP. (#198-2, at 11-15). Dr. Klinge may
 19 be incorrect about this, but that is not up to the Court to decide. See Daubert, 509 U.S. 579 at
 20 596. Therefore, Dr. Klinge can testify generally that lighter-weight, large-pore mesh is safer.

21 **C. Dr. Klinge's Opinions About Fraying and Particle Loss**


22 Ethicon argues that Dr. Klinge's opinion about Prolene Soft being defective due to fraying
 23 and particle loss should be excluded because his cited materials do not provide support for his
 24 opinion. (#198, at 11–12). Ethicon asserts that the studies Dr. Klinge references are related to
 25 TVT which is used to treat SUI and not POP. Id. Mrs. and Mr. Carter argue that the articles cited
 26 regarding the propensity of the edges of Ethicon's TVT mesh are based on the exact same cutting
 27 of the TVT textile as the Prolift textile during the manufacturing process, and thus, the mesh for
 28 SUI and POP are analogous in this way. (#204, at 10). The Court finds that Dr. Klinge is well-

1 suited to make such an analysis, and that it is based on reliable scientific methods. Ethicon can
2 cross-examine Dr. Klinge regarding the nuances within the different types of mesh and the jury
3 can weigh the evidence.

4 III. Conclusion

5 Accordingly, **IT IS HEREBY ORDERED** that Defendant's Motion to Limit Testimony of
6 Prof. Dr. Med. Uwe Klinge (#198) is **GRANTED** in part and **DENIED** in part.

7 DATED this 30 day of September 2022.

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11 Kent J. Dawson
12 United States District Judge
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